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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,391	11/17/2003	Gary L. Griffiths	40923-0005US1	2057

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,391	GRIFFITHS ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant is advised that if the invention of Group I is elected, further election is required under 35 U.S.C. 121 of one of inventions (A)-(NN) as set forth below (see item no. 4 below).

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-32 and 34-35, drawn to a method of treating a tumor-associated antigen comprising administering a non-covalently bound complex that binds a tumor-associated antigen, optionally administering a clearing agent and administering a chemotherapeutic drug or prodrug, classified in class 424, subclass 155.1.

II. Claim 2-6 and 9-35, drawn to a method of treating a virus comprising administering a non-covalently bound complex, optionally administering a clearing agent and administering a chemotherapeutic drug or prodrug, classified in class 424, subclass 147.1.

III. Claim 2-6 and 9-35, drawn to a method of treating a fungus comprising administering a non-covalently bound complex, optionally administering a clearing agent and administering a chemotherapeutic drug or prodrug, classified in class 424, subclass 152.1.

IV. Claim 2-6 and 9-35, drawn to a method of treating a parasite comprising administering a non-covalently bound complex, optionally administering a

clearing agent and administering a chemotherapeutic drug or prodrug, classified in class 424, subclass 151.1.

V. Claim 2-6 and 9-35, drawn to a method of treating a bacteria comprising administering a non-covalently bound complex, optionally administering a clearing agent and administering a chemotherapeutic drug or prodrug, classified in class 424, subclass 150.1.

VI. Claims 36-37, drawn to a kit comprising a multispecific targeting protein and a chemotherapeutic prodrug, classified in class 530, subclass 387.3.

VII. Claim 38, drawn to a method of producing a non-covalent bound complex comprising a multispecific targeting protein comprising at least one target-binding site and a hapten-binding site and a hapten-enzyme conjugate wherein said target-binding site binds to target cells and wherein said hapten-binding site non-covalently binds to said hapten-enzyme complex, thereby making a stable non-covalently bound complex, classified in class 435, subclass 69.6.

VIII. Claim 39, drawn to a method of treating a subject comprising pre-mixing a multi-specific targeting protein and a hapten-enzyme conjugate and administering said pre-mixed non-covalently bound complex to the subject, classified in class 424, subclass 136.1.

3. Claim 1 links inventions I-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 1. Upon the

allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant is advised that if any such claims depending from or including all the limitations of the allowable linking claims is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. If the invention of Group I above is elected, restriction to one of the following is also required under 35 U.S.C. 121. Therefore, in addition to the election of Group I, election is required of one of inventions (A)-(NN).

(A) AFP
(B) EGP-1
(C) EGP-2
(D) CD37
(E) CD74
(F) CSAp
(G) CEA
(H) CD19
(I) CD20
(J) CD21
(K) CD22
(L) CD23
(M) CD30
(N) CD37
(O) CD74
(P) CD80
(Q) HLA-DR
(R) HCG
(U) MUC2
(V) MUC3
(W) MUC4
(X) EGFR
(Y) HER2/neu
(Z) PAM-4
(AA) TAG-72
(BB) A3
(CC) KS-1
(DD) Le(y)
(EE) S100
(FF) PSMA
(GG) PSA
(HH) tenascin
(II) folate receptor
(JJ) VEGFR
(KK) necrosis antigen
(LL) IL-2

(S) Ia	(MM) T101
(T) MUC1	(NN) MAGE9

5. The inventions are distinct, each from the other because of the following reasons:

Inventions (A)-(NN) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions (A)-(NN) are all structurally and chemically different, have different modes of operation, different functions and effects are not disclosed as capable of use together. For example, a target-binding moiety against the EGP-1 antigen would not necessarily treat cells expressing the PSMA antigen.

The methods of Inventions I-V and VII-VIII differ in the method objectives, method steps and parameters and in the reagents used. Invention I recites a method of treating target cells comprising administering a non-covalently bound complex that binds a tumor-associated antigen, optionally administering a clearing agent and administering a chemotherapeutic drug or prodrug; Invention II recites a method of treating a virus comprising administering a non-covalently bound complex, optionally administering a clearing agent and administering a chemotherapeutic drug or prodrug; Invention III recites a method of treating a fungus comprising administering a non-covalently bound complex, optionally administering a clearing agent and administering a chemotherapeutic drug or prodrug; Invention IV recites a method of treating a parasite comprising administering a non-covalently bound complex, optionally administering a clearing agent and administering a chemotherapeutic drug or prodrug; Invention V

recites a method of treating a bacteria comprising administering a non-covalently bound complex, optionally administering a clearing agent and administering a chemotherapeutic drug or prodrug; Invention VII recites a method of producing a non-covalent bound complex comprising a multispecific targeting protein comprising at least one target-binding site and a hapten-binding site and a hapten-enzyme conjugate wherein said target-binding site binds to target cells and wherein said hapten-binding site non-covalently binds to said hapten-enzyme complex, thereby making a stable non-covalently bound complex; Invention VIII recites a method of treating a subject comprising pre-mixing a multi-specific targeting protein and a hapten-enzyme conjugate and administering said pre-mixed non-covalently bound complex to the subject. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, inventions I-V and VII-VIII are separate and distinct in having different method objectives, method steps, parameters, reagents used and different endpoints and are patentably distinct.

Inventions VI and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group VI can be used in a materially different method such as to purify the antigen in

addition to the materially different therapeutic methods of Groups I-V and VIII, which differ in the method objectives, method steps, reagents used and endpoints.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at

(571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827